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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 10/626,486

Confirmation Number: 3794

**PATENT** 

90/006,090

Applicant:

Lin

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Lee S. Cohen

Customer Number:

20,995

Commissioner for Patents Post Office Box 1450 Alexandria, Virginia 22313-1450

## DECLARATION BY JON SIEMS, M.D. UNDER 37 C.F.R. § 1.132

Sir:

- I, Jon Siems, M.D. declare as follows:
- 1. I am a research ophthalmologist with over 11 years of private practice and research experience in the field of laser vision correction surgery. I have performed several clinical investigations of a variety of different refractive surgical correction techniques, including those subsequently mentioned in Paragraphs 3 of this Declaration.
- 2. I have no financial interest in SurgiLight, Inc., which I understand to be the owner of U.S. Patent 6,623,879 ("the '879 Patent").

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- 3. I have read and understood the disclosure of the '879 Patent. I understand that this patent discloses methods of correcting presbyopia by using a laser to create incisions in the scleral tissue of a patient's eye outside the limbus to a depth of 80% to 90% of the scleral thickness. I have performed multiple clinical investigations relating to presbyopia correction techniques, including investigations of certain of the methods disclosed in the '879 Patent.
- 4. I have read and understood an article authored by Spencer P. Thornton entitled "Anterior Ciliary Sclerotomy (ACS), A Procedure to Reverse Presbyopia". A copy of this article, which appeared in Sher, Surgery for Hyperopia & Presbyopia, October 1997, Williams & Wilkins, First Edition, pages 33–36, is attached to this Declaration as Appendix A. I understand that this article discloses surgical procedures to treat presbyopia by using a blade to create incisions into the sclera over the ciliary body to a depth of 65% to 70% of the scleral thickness.
- 5. In the course of my study of the presbyopia correction techniques referred to in Paragraph 3 of this Declaration, I have come to the conclusion that the effectiveness of these techniques depends, among other things, on the incision depth. In particular, published literature has shown that if the Thornton procedure was performed and incision depth is less than about 70% of the scleral thickness, significant regression occurs after the correction procedure is performed. This regression occurs within three to six months of performing the procedure. When such regression occurs, the corrective procedure provides the patient with little or no clinical benefit. Therefore, in my opinion and that of the ophthalmic community, the surgical techniques disclosed in the Sher article referred to in Paragraph 4 of this Declaration yield poor clinical results and provide the patient with little or no clinical benefit.
- 6. In the course of my study of the presbyopia correction techniques referred to in Paragraph 3 of this Declaration, I have come to the conclusion, based on data

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derived from available two year follow-up results from the clinical trial, if the incision depth is greater than or equal to about 80% of the scleral thickness, little or no regression occurs after the correction procedure is performed, even up to several years after the procedure. Therefore, in my opinion, the surgical techniques disclosed in the '879 Patent provide the patient with significantly better clinical results (as compared to the surgical procedures disclosed in the Sher article referred to in Paragraph 4 of this Declaration) and a substantial clinical benefit.

7. All statements made herein of my own knowledge are true. All statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the above-referenced patent application or any patent issued thereon.

Respectfully submitted

Stems, M.D.

Dated:

2/13/06

By:

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